HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95071d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-03

October 19, 2004

Bo Andersson, President
Computerized Radiation Scanners, Inc.
140 Sopwith Drive
Vero Beach, Florida 32968-9219

Dear Mr. Andersson:

During an inspection of your establishment located at 140 Sopwith Drive, Vero Beach, Florida on July 19 -20, 2004, FDA Investigator R. Kevin Vogel determined that your firm manufacturers radiation beam scanners, which are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. 321(h)].

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), part 820. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. §351(h)] of the Act. The investigator noted the following violations of the QS regulations:

1. Each manufacturer shall establish procedures for quality audits and conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. Your firm failed to conduct internal audits at sufficient regular intervals since 1999-2000 even though your internal audit procedure requires that such audits be done on an annual basis. Your audit procedures also fail to address essential criteria including: purchasing control, process validation (software validation), design control, corrective and preventive action (CAPA), and Medical Device Reporting (MDR) (FDA 483, Items #3 & 4).

2. Each manufacturer of a Class II device shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30(a). Procedures to control the design process of the device are not documented (FDA 483, Item #1).

3. Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and, shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. All results of the design validation including the identification of the design, method(s), the date, and the individual(s), performing the validation, shall be documented in the Design History File (DHF) as required by 21 CFR 820.32(g). The results of design validation including identification of the design methods, the date, and the individual performing the validation were not documented in the DHF. Your firm also failed to document risk analysis or design input associated with a software design change related to complaints dated 5/13/2004 and 11/27/2003. There was no documentation covering the change of a resistor and a design change to the electrometer to assure the changes did not adversely affect the performance of the finished device (FDA 483, Items #5 & 6).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps that you are still in the process of taking to correct the noted

violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

for Emma Singleton
Director, Florida District